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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

ABBOTT DIABETES CARE, INC. and ABBOTT LABORATORIES,

Plaintiffs/Counterdefendants,

v.

ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC. and BAYER HEALTHCARE LLC,

Defendants/Counterplaintiffs.

CASE NO. 05-CV 3117 MJJ

ROCHE'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 6,592,745

Date: December 12, 2007
Time: 10:00 a.m.
Place: Courtroom 11, 19th Floor
Judge: Hon. Martin J. Jenkins

PUBLIC VERSION

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I. INTRODUCTION.

PLEASE TAKE NOTICE that on December 12, 2007, at 10: a.m., or as soon thereafter as the matter may be heard, in the Courtroom of the Honorable Martin J. Jenkins, Courtroom 11, 19th Floor, Philip E. Burton Courthouse and Federal Building, 450 Golden Gate Avenue, San Francisco, California, Defendants/Counterplaintiffs, ROCHE DIAGNOSTICS CORPORATION and ROCHE DIAGNOSTICS OPERATIONS, INC. ("Roche"), Motion for Partial Summary Judgment of Non-Infringement of United States Patent No. 6,592,745 ("the '745 Patent") will be heard.

The undisputed facts demonstrate that the Aviva does not infringe the '745 Patent for at least two reasons: (1) it lacks the claimed redox mediator; and, (2) it lacks the claimed measurement zone. As to the mediator:

- Abbott and Roche have agreed claims 1, 28, and 34 of the '745 Patent -- the only independent claims -- require the electrochemical sensor to include a diffusible redox mediator before the sample touches the electrochemical sensor.
- In its Final Infringement Contentions, Abbott admits that the Aviva strips contain a [redacted] before the blood sample is applied and that the mediator, [redacted] is not formed until after the blood sample is applied. Roche's 30(b)(6) witness and Abbott's experts agree.
- In its Final Contentions, Abbott has alleged only literal infringement of the '745 patent. Abbott has not alleged the mediator is present under the doctrine of equivalents.

As to the measurement zone:

> The '745 claims a method for determining a concentration of glucose in a sample by using an electrochemical sensor comprising, *inter alia*:
>
> > ...(ii) a measurement zone positioned adjacent to the working electrode and the counterelectrode, wherein the measurement zone is sized to contain a volume of no more than about one microliter of the sample.
>
> Further, the inventors of the '745 Patent, acting as their own lexicographers, specifically defined the measurement zone as:

> a region of the sample chamber *sized* to contain *only* that portion of the sample that is to be *interrogated* during an analyte assay. '745 Patent, Col. 7: 7-9 (emphasis added).

- [redacted]
- Abbott has no evidence, however, in its expert reports or elsewhere, that the Aviva strips include a physical space that "contain[s] only that portion of the sample that is to be interrogated during an analyte assay." [redacted]

In short, the undisputed facts demonstrate that the Aviva strip lacks at least two elements of each asserted claim of the '745 Patent. Thus, the Court should grant summary judgment of non-infringement of the '745 Patent by Roche's Aviva system.

II. UNDISPUTED FACTS.

A. Overview of The '745 Patent

The '745 Patent discloses a method for determining the concentration of glucose in a sample. *See, e.g.*, Tyler Dec. Ex. 1 at claims 1 and 28. *See also id.* at claim 34 (claim for determining the concentration of an analyte in a sample). This method involves contacting a sample of blood or other biological fluid with an electrochemical sensor. *See, e.g., id.* at claim 1. The sensor includes two electrodes, a measurement zone, an analyte-responsive enzyme, and a diffusible redox mediator. *Id.* The patent expressly defines a "redox mediator" as "an electron transfer agent for carrying electrons between the analyte and the working electrode, either directly, or via a second electron transfer agent." *Id.* at Col. 7:21.[1]

The '745 Patent claims that the use of an electrochemical sensor for measuring glucose in a small volume can introduce error into the measurements. *See id.* at 1:42-47. One type of error allegedly arose from using a diffusible redox mediator with closely spaced electrodes, which makes it possible that the mediator will shuttle between the two electrodes. *Id.* at 1:48-52. This

"mediator shuttling" between the working and counter electrodes can create a background current and lead to an erroneous glucose reading by adding to the signal measured for the glucose. *See id.*; Tyler Dec. Ex. 5 at 66-67. The '745 Patent purports to offer an approach to decreasing the errors allegedly associated with the size of the sensor and sample. *See* Tyler Dec. Ex. 1 at 1:58-59.

B. Claim Construction For Claims 1, 28, and 34

In April, 2007, the Court issued its claim construction order, settling the construction of the disputed claim terms and adopting the agreed-to construction of the undisputed terms of the '745 and '551 patents. Docket No. 391. One key portion of the '745 Patent claim language states: "contacting a sample with an electrochemical sensor comprising: (i) an electrode pair..., (ii) a measurement zone... and, (iii) an analyte-responsive enzyme and a diffusible redox mediator." *See* Tyler Dec. Ex. 1 at claims 1, 28, and 34. Abbott and Roche agreed this language means "[a]n electrochemical sensor, which includes two electrodes, a measurement zone, an analyte-responsive enzyme and a diffusible redox mediator, to which electrochemical sensor a sample is touched." Docket No. 89, Revised Joint Preliminary Claim Construction Statement '745 Patent, March 30, 2006, at 1.

The parties adopted the patent's express definition of measurement zone as "a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during an analyte assay." *Id.* and Tyler Dec. Ex. 1 at Col. 7:7-9.

C. The Roche Accu-Chek® Aviva System

The Roche Aviva electrochemical sensor, which includes a meter and test strip, is used to determine the concentration of glucose in a sample of blood. Tyler Dec. Ex. 5 at 32:9-12. The Aviva test strip includes a working and counter electrode, which are coated with the enzyme

[1] The patent defines a "second electron transfer agent" as "a molecule that carries electrons between a redox mediator and the analyte." '745 Patent, Col. 7:31-32. In other words, the second electron transfer agent is the enzyme. Tyler Dec. Ex. 3 at 29:16-20.

[redacted] at the time of manufacture. *Id.* at 57:16–58:2. In addition, the electrodes are also coated with [redacted]. *See* Tyler Dec. Ex. 6 at Roche00000153 (showing the chemical formulas and reactions associated with the operation of the Aviva); Tyler Dec. Ex. 5 at 57:16-20 (stating that the electrodes "are coated with something that can be made into a mediator but it is not a mediator"). When blood containing glucose is applied to the Aviva test strip, the glucose reacts with the enzyme and [redacted]. The [redacted]. *See* Tyler Dec. Ex. 5 at 64:1-10; Tyler Dec. Ex. 6 at Roche 00000153; and Tyler Dec. Ex. 3 at 31:22 - 32:21 and 33:9 - 35:5. The [redacted] transfers electrons obtained from the glucose to the working electrode to generate a current that is representative of the concentration of glucose in the blood sample. *See* Tyler Dec. Ex. 5 at 83:17-25; Ex. 3 at *id*; Ex. 9 at 245:23 - 246:24.

The Aviva system uses the mediator to determine the level of glucose, but the mediator is not present before blood is applied. Tyler Dec. Ex. 5 at 64:1-5 and 79:25–80:8. The '745 patent recognizes that "the redox mediator [can be] in a mixed oxidation state (i.e., some redox centers in the reduced state and some in the oxidized state) prior to the introduction of the sample...." Tyler Dec. Ex. 1 at 49:54-56. That is, a mediator "can be unstable and can react in the absence of glucose leading to blank current and erroneous results." *Id.* at 79:22-24. As a result, the Aviva was consciously designed so that a mediator is not present on the Aviva test strip before blood is applied. *Id.* at 79:25–80:8; Tyler Dec. Ex. 3 at 31:15-18 and 33:6 - 34:5. Dr. Nigel Surridge, a Roche scientist who headed the Aviva development team, stated one reason for choosing this design:

[redacted]

[redacted] Tyler Dec. Ex. 5 at 79:25-80:8; Ex. 9 at 248:21 - 250:15. Because it is not a mediator, the [redacted] does not carry electrons between the glucose and the working electrode, either directly or through the enzyme. *Id.* at 241:1-5; Tyler Dec. Ex. 3 at 32:13-21 and 33:17 - 34:2 [redacted] carries electrons to working electrode). Nor is it capable of shuttling back and forth between the electrodes. Tyler Dec. Ex. 5 at 241:10-13; Tyler Dec. Ex. 3 at 42:9-12. Instead, the [redacted] provides a necessary component to the chemical reaction that forms the mediator. Tyler Dec. Ex. 5 at 241:7-9. The patent states that "[t]he background signal corresponds to the charge passed in an electrochemical assay in the absence of the analyte," Tyler Dec. Ex. 1 at 9:57-59, *i.e.*, glucose. In the Aviva, there is no such background signal from the redox mediator because glucose must be present to react with [redacted] for the redox mediator even to form.

As to the measurement zone, Abbott's expert and only infringement witness for the '745 Patent, Dr. Allen J. Bard, testified that [redacted]. Tyler Dec. Ex. 3 at 125:24 - 126:21; 133:22 - 134:13; 135:18 - 136:2; and 283:11-15; Tyler Dec. Ex. 4 at 312:15 - 313:16, 317:14 - 321:21. Abbott has identified no evidence that the Aviva has a measurement zone as defined in the '745 Patent.

D. Abbott's Final Infringement Contentions

Abbott submitted Final Infringement Contentions on May 29, 2007. *See* Tyler Dec. Ex. 2 (Abbott's Final Infringement Contentions -- Roche). These included significant changes from the Preliminary Infringement Contentions of August 18, 2006. The Final Contentions made express

contentions of infringement under the doctrine of equivalents for the mediator element of the '551 patent, but not for the mediator element of the '745 Patent. *See* Tyler Dec. Ex. 2 at Ex. 1, pp. 6-7.

1. Final Infringement Contentions – '745 Patent

Abbott contended in their Final Infringement Contentions for the '745 Patent that the Aviva has electrodes "made of gold and include a coating containing an enzyme and mediator precursor." *Id.* at Ex. 2 pp. 24, 84 (same for claim 28), and 124 (same for claim 34). Abbott also contended that the mediator of the Aviva test strip is [redacted]. *Id.* at pp. 34 (claim 1), 94 (claim 28), and 134 (claim 34).

Abbott did not contend that the Aviva infringed the '745 Patent under the doctrine of equivalents. *Cf. id.* and *id.* at Ex. 1 pp. 6-7 (alleging infringement of the '551 patent under the doctrine of equivalents).

2. Final Infringement Contentions – '551 Patent

Abbott contend in the Final Infringement Contentions for the '551 patent that the Aviva test strip includes an active electrode that "has a mixture of enzyme and mediator precursor coated on the surface of the piece of metal." *Id.* at Ex. 1 p. 3. Abbott also contended that the counter electrode "has a mixture of enzyme and mediator precursor coated on the surface of the piece of metal." *Id.* at p. 5. Abbott then contended that the active electrode of the Aviva is coated with a mediator. *Id.* at p. 6 ("Although Roche asserts that the [redacted] initially coated on the Aviva Strip is not a mediator, it admits that it becomes a [redacted] mediator after blood is applied to the strip."). Abbott further expressly contended the Aviva infringed the '551 patent under the doctrine of equivalents, stating that:

> Alternatively, the [redacted] initially coated on the Aviva Strip is equivalent to a mediator because it becomes a mediator upon contact with blood. This is an insubstantial difference because the mediator precursor turns into a mediator which performs the same function of transferring electrons to the active electrode

> during the measurement as is performed by the mediator recited in the claim. Doing so creates a current just as occurs with the mediator recited in the claim.

Id. at pp. 6-7.

III. ARGUMENT.

A. The Summary Judgment Standard

Fed. R. Civ. P. 56 states that the Court shall enter judgment as a matter of law on any claim where "the pleadings, depositions, answer to interrogatories, and admissions on file, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In determining whether summary judgment is proper, the Court construes the evidence in favor of the non-movant. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A court "gives credence to the evidence favoring the non-movant as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached....'." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). To defeat a summary judgment motion, the non-movant must do more than raise "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986). Thus, a scintilla of evidence in favor of the non-movant is insufficient to preclude summary judgment. *Anderson*, 477 U.S. at 252.

Stated another way, the non-movant avoids summary judgment only where that party "presents evidence such that, if the trial record were the same as the summary judgment record, a fact finder could reasonably find in the nonmovant's favor." *Hall v. Aqua Queen Mfg., Inc.*, 93 F.3d 1548, 1553 n.3 (Fed. Cir. 1996) (citing *Matsushita*, 475 U.S. at 587).

Further, given that Abbott bears the burden of proof on infringement, the Court should grant summary judgment in favor of Roche if Abbott has no admissible evidence to prove an essential element of its claim:

> In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is "entitled to a judgment as a matter of law" because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.

Celotex Corp. v. Catrett, 417 U.S. 317, 322-23 (1986).

Summary judgment is as appropriate in patent infringement cases as it is in any other type of case. *See, e.g., Transmatic, Inc. v. Gulton Indus., Inc.*, 53 F.3d 1270, 1274 (Fed. Cir. 1995); *Nike, Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994).

B. The Law of Infringement

The analysis of patent infringement consists of two separate steps: claim interpretation and comparison of the accused product to the claims. *Jurgens v. McKasy*, 927 F.2d 1552, 1560 (Fed. Cir. 1991). First, the Court construes the claims as a matter of law to establish their meaning and scope. *Markman v. Westview Instruments*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 116 S. Ct. 1384 (1996). Second, the trier of fact determines whether the claims as thus construed read literally on the accused product, or if the accused product has a substantial equivalent for each claim element not literally met. *Southwall Techs. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). Where, as here, only literal infringement is alleged, "literal infringement requires that the allegedly infringing device embody every element of a patent claim." *Mannesmann Demag Corp. v. Engineered Metal Prod. Co.*, 793 F.2d 1279, 1282 (Fed. Cir. 1986).

Plaintiffs may, without leave of the Court, submit "Final Infringement Contentions" alleging that each element of each asserted claim is present literally or under the doctrine of equivalents no later than 30 days after service by the Court of its claim construction order. Patent

L.R. 3-6(a). Abbott did so, but did not contend infringement of the mediator or measurement zone element of the '745 Patent under the doctrine of equivalents. After that date, the Final Infringement Contentions can only be amended based upon a showing of good cause. Patent L.R. 3-7. Despite being on notice of at least Roche's argument that the Aviva lacks the claimed redox mediator before the blood is applied, *see* Docket No. 439 at 5, Abbott has made no effort to amend this portion of its Final Infringement Contentions - Roche.

C. To Literally Infringe the '745 Patent, a Mediator Must Be Present On the Aviva Test Strip Prior To Touching the Sample To The Test Strip

Abbott and Roche agreed that the claims of the '745 Patent require the mediator to be present on the Aviva test strip prior to the application of the blood sample to the test strip. *See* Docket No. 89, Revised Joint Preliminary Claim Construction Statement '745 Patent, March 30, 2006, at 1 ("*An electrochemical sensor, which includes* two electrodes, a measurement zone, an analyte-responsive enzyme and *a diffusible redox mediator, to which electrochemical sensor a sample is touched.*" (emphasis added)). Under this construction of claims 1, 28, and 34, prior to ever coming into contact with a sample, an infringing electrochemical sensor must include:

- Two electrodes;
- A measurement zone;
- An analyte-responsive enzyme; and
- A diffusible redox mediator.

An electrochemical sensor that does not include each and every element before it touches the sample does not literally infringe. *See Warner-Jenkinson*, 520 U.S. at 40 (stating that each and every element of the claim must be present to infringe). Thus, the mediator must literally be present before the sample is applied for the Aviva to infringe. *See Mannesmann*, 793 F.2d at 1282. *Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1253 (Fed. Cir. 1998) (accused device that did not have claimed element at the time "when" it was required by claim did not infringe). If the mediator forms only following contact with the sample, then the mediator

was not present prior to contact with the sample and such a device cannot literally infringe claims 1, 28, and 34.

D. The Aviva System Does Not Literally Infringe The '745 Patent Because A Mediator Is Not Present On The Aviva Test Strip Prior To Contact With The Sample

The undisputed facts, including Abbott's Final Contentions, show that a redox mediator as defined by the '745 Patent is not present on the Aviva test strip prior to contact with the sample; as a result, the Aviva does not literally infringe the '745 Patent. Abbott and Roche agree that prior to contact with the sample the Aviva test strip contains "an enzyme and a mediator precursor." The mediator precursor is [redacted]. Abbott and Roche further agree that the actual mediator is [redacted]. Thus, it is undisputed that [redacted] is the mediator precursor and [redacted] is the redox mediator of the Aviva test strip.

The undisputed facts further show that the [redacted] forms only after the sample contacts the Aviva test strip; it is not present before the strip contacts the sample. Claims 1, 28, and 34 of the '745 Patent require the mediator to be present *before contact* with the sample, but the undisputed facts establish that the Aviva mediator is formed *only after contact* with the sample. For at least this reason, the Aviva test strip cannot literally infringe the claims of the '745 Patent because the device does not embody every element of the claims. *See Mannesmann*, 793 F.2d at 1282; *Renishaw*, 158 F.3d at 1253.

It is also undisputed that the Aviva mediator precursor does not perform the functions of the '745 Patent mediator, which again illustrates that this element of the '745 Patent is missing from the Aviva strip. According to the '745 Patent, the mediator that is present in the sensor before touching the sample is "an electron transfer agent for carrying electrons between the analyte and the working electrode." Tyler Dec. Ex. 1 at Col. 7:21. A mediator can also "shuttle" between the working and counter electrodes, which can create inaccuracy by creating current that

adds to the current generated by the reaction with glucose. *Id.* at 1:48-52. In the Aviva strip, only the [redacted], which form after contact with the sample, performs these functions.

The [redacted] of the Aviva test strip performs neither of these functions of the '745 Patent mediator. It does not act as an electron transfer agent to transfer electrons from glucose to the working electrode. Nor is the [redacted] capable of shuttling and erroneously adding to the signal measured for the glucose. Further, the [redacted] is stable, so before blood that contains glucose is applied it does not create a reduced form, which can lead to errors as described in the '745 Patent at Col. 49:54-57. Because the [redacted] does not react in the absence of glucose, it does not create any "background signal correspond[ing] to the charge passed in an electrochemical assay in the absence of the analyte." Tyler Dec. Ex. 1 at Col. 9:57-58. In other words, [redacted] does not create the background signal that is relevant to the claims of the patent - background signal from the redox mediator in the absence of glucose. *E.g., id.* and Col. 61:56-61 (claim 1). The undisputed facts show that [redacted] does not perform the mediator functions defined by the '745 Patent. Only the [redacted], which are formed after contact with the sample, perform these functions on the Aviva test strip. Thus, the Aviva cannot infringe the '745 Patent because it does not possess all of the elements of the claims.

E. Abbott Did Not Assert The Doctrine of Equivalents

Abbott has not contended that the mediator element is infringed under the doctrine of equivalents. Specifically, while Abbott expressly contended in its Final Infringement Contentions that the "mediator" element of claims 1, 28, and 34 is literally present in the Aviva, Abbott did not contend that it is present under the doctrine of equivalents.

In its Final Infringement Contentions, Abbott expressly contended that the mediator element of the '551 Patent is present in the Aviva literally or under the doctrine of equivalents. Abbott first contended the Aviva literally infringed the '551 Patent because the "active electrode is also coated with a mediator." Abbott then contended that "[alternatively], the [redacted] initially coated on the Aviva Strip is *equivalent* to a mediator because it becomes a mediator upon contact with blood." Tyler Dec. Ex. 2 at Ex. 1 pp. 6-7 (emphasis added). In contrast, Abbott alleged the Aviva literally infringed the '745 Patent simply because the "mediator [of the Aviva] is [redacted]," which Abbott admits is not present before the sample touches the strip. Unlike the Final Infringement Contentions for the '551 Patent, Abbott did not allege that the [redacted] initially present on the Aviva test strip is *equivalent* to a mediator. Nor did Abbott allege that the [redacted] performed substantially the same function in substantially the same way to achieve substantially the same result as the mediator element of the '745 Patent. The fact that Abbott alleged infringement under the doctrine of equivalents for the '551 Patent, but not for the '745 Patent, and has not sought to amend its contentions, shows that the omission was deliberate.

Abbott cannot now contend that the Aviva system infringes the '745 Patent under the doctrine of equivalents. Where a patentee fails to provide the information required by Patent Local Rule 3-1(d) for a theory of infringement by the doctrine of equivalents, it is precluded from pursuing claims based upon such a theory. *See Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761, 773-74 (Fed. Cir. 2000) (affirming the district court's ruling that the patentee was precluded from proceeding on a theory of infringement under the doctrine of equivalents because it had not expressly included such theory in its claim chart required by Civil Local Rule 16-9 of the Northern District of California)[2]; *Berger v. Rossignol Ski Co., Inc.*, 2006 WL 1095914, at *2-6 (N.D. Cal. 2006) (limiting the patentee to the literal infringement theory actually contained in its

infringement contentions and granting summary judgment of non-infringement); *MEMC Elec. Materials v. Mitsubishi Materials Silicon Corp.*, 2004 WL 5363616 at *4-6 (N.D. Cal. 2004) (granting the accused infringer's motion to preclude the patentee from pursuing its claim of infringement under the doctrine of equivalents and barring the patentee from offering any expert report or testimony that the accused infringer infringed under the doctrine of equivalents because the patentee failed to include such a claim in its infringement contentions);[3] *Atmel Corp. v. Information Storage Devices, Inc.*, 1998 WL 775115, *1-3 (N.D. Cal. 1998) (refusing to allow the patentee to amend the claim chart required by Civil Local Rule 16-9 to assert a theory of infringement based upon the doctrine of equivalents in response to a motion for summary judgment of non-infringement).

F. Abbott Has Identified No Admissible Evidence that the Aviva Strip Contains a Measurement Zone As Defined by the '745 Patent

The '745 claims a method for determining a concentration of glucose in a sample by using an electrochemical sensor comprising, *inter alia*:

> ...(ii) a measurement zone positioned adjacent to the working electrode and the counterelectrode, wherein the measurement zone is sized to contain a volume of no more than about one microliter of the sample.

Tyler Dec. Ex. 1 at Col. 61, lines 48-51.

Further, the inventors of the '745 Patent, acting as their own lexicographers, specifically defined the measurement zone as:

> a region of the sample chamber sized to contain only that portion of the sample that is to be interrogated during an analyte assay.

[2] Civil Local Rule 16-9 was the predecessor of Patent Local Rule 3-1. *See MEMC*, 2004 WL 5363616 at *4, n.3.

[3] Dr. Bard's report claims that the [redacted] in the Aviva system is equivalent to a mediator. Tyler Dec. Ex. 7 at 10-11. Under the *MEMC* case, the Court should preclude Abbott from presenting any expert testimony to this effect. Further, this portion of Dr. Bard's report does not preclude summary judgment because it is wholly conclusory. *On-Line Techs, Inc. v Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1144 (Fed. Cir. 2004) ("conclusory assertions by expert witnesses are not sufficient to avoid summary judgment"); *Arthur A. Collins, Inc. v. Northern Telecom Ltd.*, 216 F.3d 1042, 1046-47 (Fed. Cir. 2000 (same).

Id. at Col. 7, lines 7-10. Abbott agreed to this definition in the parties' Second Joint Claim Construction Submission Pursuant to Local Rule 4-3, at 156.

Abbott's '745 infringement expert, Dr. Allen Bard, and Roche's expert, Dr. Stephen Weber, agree that the measurement zone is [redacted]. Notwithstanding this agreement and the agreed definition of "measurement zone," however, Abbott has no evidence that the Aviva strip includes [redacted] "contain[s] only that portion of the sample that is to be interrogated during an analyte assay." Dr. Bard's report does not state there is [redacted] in the Aviva strips that is sized to contain only that portion of the sample "interrogated" during the assay, as required by the '745 Patent's explicit definition of measurement zone. Tyler Dec. Ex. 7 at pp. 7-9, parts 3 and 4. Indeed, Dr. Bard's report is silent on what portion of the sample in the Aviva strips is interrogated during the analyte assay. Instead, his validity report claims that [redacted] Tyler Dec. Ex. 8 at 12. Further, during his deposition Dr. Bard testified that to determine where the measurement zone is -- where the sample is interrogated -- in the Aviva strips he would have to [redacted] Abbott and Dr. Bard simply ignore this part of the patent's express and the parties' agreed definition of measurement zone. Thus, Abbott has a complete failure of proof under *Celotex,* 477 U.S. at 322-23, as to the required measurement zone element, and summary judgment for Roche is proper.

Finally, Roche's expert, Dr. Stephen Weber, discusses this issue in his report in extensive detail and concludes that, under the only reasonable interpretation of measurement zone in the '745 Patent, it does not cover any measurement zone for Roche's accused amperometric system with co-planar electrodes because the Aviva does not have [redacted] Weber Dec. Ex. 2 at 35-42. Abbott provides no contrary evidence on this issue. Abbott has no evidence of where the sample in the Aviva

strips is interrogated, and thus no evidence that there is a physical space in the Aviva strips that contains only the portion of the sample to be interrogated during the test. This is a second, independent reason the Court should enter summary judgment of non-infringement of the '745 Patent in favor of Roche.

IV. CONCLUSION.

For these reasons, the Court should grant summary judgment in favor of Roche of non-infringement of the '745 Patent. To literally infringe the '745 Patent, the agreed construction of the claims requires the mediator to be present in the electrochemical sensor *prior to* contact with the sample, but the undisputed facts show that the mediator of the Aviva test strip forms only *after* contact with the sample. Similarly, the '745 Patent defines the measurement zone as a [redacted] that "contain[s] only that portion of the sample that is to be interrogated during an analyte assay." Abbott has no evidence that the Aviva strips [redacted] satisfies this definition and thus cannot prove an essential element of its claim. Abbott has not alleged infringement of these elements of the '745 Patent under the doctrine of equivalents. Thus, Roche's Aviva system does not infringe the '745 Patent because as a matter of law it lacks at least two elements of every claim.

Respectfully submitted,

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